UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
BOEHRINGER INGELHEIM ANIMAL HEALTH, INC.,	)	**Docket No. FIFRA-93-H-11**
	)	
	)	
Respondent	)	

ORDER DENYING RESPONDENT'S MOTION TO REDUCE COUNTS IN THE COMPLAINT FROM FOUR TO ONE

On April 19, 1993, the Environmental Protection Agency (sometimes complainant or Agency) served a complaint upon Boehringer Ingelheim Animal Health, Inc. (respondent) alleging that it failed to comply with various provisions of the Good Laboratory Practice Standards (GLPS), 40 C.F.R. Part 160, when it submitted an application for registration of a pesticide. The study submitted to the Agency in support of this application was conducted by P.A.C.E. International, an independent testing facility.

Respondent sponsored this study as defined by 40 C.F.R. § 160.3 (1992) and submitted a statement of compliance as required under 40 C.F.R. § 160.12 (1992). Complainant seeks an $18,000 penalty pursuant to section 12(a)(2)(Q) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136j(a)(2)(Q), for four alleged violations of the GLPS. Specifically, complainant alleges that respondent failed to retain all raw data, documentation, records, protocols, specimens and final reports generated as a result of the study as required by 40 C.F.R.

§ 160.190(a); that it failed to insure that all data entries were dated on the date of entry and signed or initialed by the person entering the data or that all changes were made so as not to obscure the original; that it did not indicate reasons for the changes and did not date or sign or initial same at the time, as required by 40 C.F.R. § 160.130(e); that respondent's testing facility failed to document changes in or revisions to approved protocol and reasons for same and failed to have the study director sign and date such documentation, and failed to maintain this documentation with the test protocol as required by 40 C.F.R. § 160.120(b); and that respondent failed to determine that no deviations from the approved protocols or standards were made without proper authorization and documentation as required by 40 C.F.R. § 160.35(b)(5).

Respondent submitted a signed statement that the study in support of the application was conducted in compliance with GLPS regulations. Complainant maintains that the study accompanying this statement diverges from the regulations in various respects, and that each aspect gives rise to a separate violation. Respondent is of the opinion that since only one study has been made and a single statement of compliance submitted, there can be only one violation. For the reasons stated in its motion served May 7, 1993, respondent moved to reduce the alleged four violations to one count. Complainant served its response in opposition to this motion on May 17, 1993.

Respondent's Position

The essence of respondent's argument is that "[o]nly one study and a single compliance statement are at issue in this matter." (Mot. at 1.) The stated authority for this position is an order issued In the Matter of Bio-Tek Industries (Bio-Tek), Docket No. FIFRA-92-H-06, (Apr. 13, 1993). That proceeding concerned two applications for pesticide registration. As in this case, the Agency alleged that a violation occurred every time a GLPS requirement was not met. In a conclusion favoring respondent, Bio-Tek stated:

> . . . a single statement or piece of information, which is false in more than one respect, submitted to the Agency in connection with a single transaction . . . may not be turned into multiple violations for which multiple penalties may be assessed.

Bio-Tek at 21. Respondent contends that, under the authority of Bio-Tek, there can be only a single violation for the submission of a "single" false statement under FIFRA. Moreover, respondent argues that this is true regardless of how many GLPS digressions have occurred in connection with the study. (Mot. at 1.) Accordingly, respondent asserts that it could not be assessed a penalty of more than $5000.

To more fully understand respondent's position, an examination of Bio-Tek is appropriate. At issue there were so called "derivative" statements used to fulfill the "Statement of Compliance or Noncompliance" requirement set forth in 40 C.F.R. § 160.12. A derivative statement is one which does not itself make a representation that all requirements were met, but refers to a

statement made by a testing facility which makes such representations. Thus, Bio-Tek held that if that study was false in any respect "it can only be because Bio-Tek's submission of the studies constituted representations the studies were conducted in conformance with GLPS." It was held further that statements of compliance are indeed representations. Bio-Tek at 12, 13-15. Moreover, it concluded that respondent understood that the submission of its statement and study held out to the Agency that the document was in compliance and that the signer would be held responsible for its representation. Bio-Tek at 12-13, 15.

It followed that the next question was whether the separate submissions could each be the basis of multiple violations. An examination of the relevant language, histories and case law was made. The statute, section 12(a)(2)(Q) of FIFRA, provides that:

> (2) It shall be unlawful for any person--
> (Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter;

7 U.S.C. § 136j(a)(2)(Q). The legislative history is sparse and provides, in relevant part, as follows: "Unlawful acts -- provides that certain acts (such as submitting false test data . . .) will be unlawful." H.R. 100-939, at 26 (1988), reprinted in U.S.C.C.A.N. at 3475, cited in Bio-Tek at 16. From this language it was concluded that "[t]here is no indication that Congress in

enacting section 12(a)(2)(Q) intended to impose multiple penalties, because 'all or part of any information relating to testing of any pesticide' was false in more than one aspect." Bio-Tek at 17. "[T]he report merely repeats the language of the amendment and provides no explanation or rationale for the language used." Bio-Tek at 16. Other FIFRA provisions were examined to find an analogous situation. Misbranding was selected, with the rationale being that there is no more reason to conclude that multiple penalties are available here than to make that conclusion with regard to misbranding violations. Bio-Tek at 17, citing In re Hawk Industries (Hawk), Docket No. I.F.R.-II-120C, (Dec. 21, 1976).

Once it made clear that the statute is ambiguous, Bio-Tek held that well established legal principles mandate that ambiguity be resolved in favor of lenity. Bio-Tek at 17 (citing Heflin v. United States, 358 U.S. 415 (1959), and other criminal multiple penalty cases). The test embodying this principle to determine whether multiple counts are appropriate asks whether each count requires proof of a fact the other does not. Blockburger v. United States (Blockburger), 284 U.S. 299 (1932), cited in Bio-Tek at 17, held that there could be more than one violation of a narcotics act when different facts had to be used for each count. The Agency has

expressly adopted this test in the 1974 Guidelines for the Assessment [of Civil Penalties] Under FIFRA § 14(a)[1] and the 1990 Enforcement Response Policy (ERP) for FIFRA.[2] Bio-Tek at 19.

According to Bio-Tek, however, the 1991 ERP for FIFRA GLP Regulations[3] departs from this norm in creating separate counts

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[1] The relevant portion of the 1974 guidelines provides that:
> A separate civil penalty shall be assessed for each violation . . . which results from an independent act (or failure to act) of the respondent which is substantially distinguishable from any other charge in the complaint for which a civil penalty is to be assessed. [To determine] whether a given charge is independent and substantially distinguishable . . . for the purpose of assessing separate penalties, complainant must consider whether each provision requires an element of proof not required by the other.

39 Fed. Reg. 27,711 (July 31, 1974).

[2] The FIFRA ERP issued July 2, 1990, provides:

> Independently Assessable Charges:
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> A separate civil penalty . . . shall be assessed for each violation of the Act. A violation is independent if it results from an act (or failure to act) which is not the result of any other charge for which a civil penalty is to be assessed, or if the elements of proof for the violations are different. Dependent violations may be listed in the complaint, but will not result in separate civil penalties.

Enforcement Response Policy for FIFRA at 25 (July 2, 1990).

[3] The ERP for the FIFRA GLP, issued September 30, 1991, provides:

> Multiple Violations:
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> A statement, under 40 C.F.R 160.12, which certifies that a study complies with the GLPs is a statement that all requirements listed in 40 C.F.R. 160 have been met. If requirements of the GLPs have not been met, then the GLP compliance statement is false. Each independent requirement of the GLPs which has been violated, but has been represented through the statement as in compliance,

(continued...)

though there is only one "statement." Complainant argues that it would be ludicrous to force applicants for registration to file each separate piece of information on a separate form. (Opp'n at 30.) Bio-Tek maintains, however, that, absent notice and comment rulemaking, the public cannot be said to be on notice that there are separately assessable violations when this one single form is submitted. Bio-Tek at 20. It concludes that "the essence" of the violation is the submission of a false statement and absent some indicia from Congress or published regulations that these provisions should be read otherwise, a single "statement" can lead to only one violation. Bio-Tek finds that the Agency's attempt to turn this into multiple violations is arbitrary. Bio-Tek at 21.

Complainant's Opposition

Complainant here urges that the reasoning in Bio-Tek is defective and its conclusion is in error. It maintains that a report is not "a single statement," as if it "comprised only a single, indivisible piece of information." Complainant reasons that, from this initial misstep, Bio-Tek applied the wrong case law. (Opp'n at 2.)

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[3](...continued)
may be considered a separate count of FIFRA section 12(a)(2)(M) or 12(a)(2)(Q), as appropriate, and each count assessed a civil penalty . . . (see the July 2, 1990 FIFRA ERP, page 25, for a discussion of independently assessable charges).

Enforcement Response Policy For The FIFRA Good Laboratory Practice Regulations (Sept. 30, 1991) at 7.

A. A Single Statement

Complainant's first argument centers upon the nature of false "information." Its position is that each study contains many kinds of information which serve varied purposes; and that when a company submits a study, it is representing that all the particular, independent requirements of the GLPS are being met. It argues that all or any part of those requirements can be false without affecting other requirements. Id. at 2-3.

Complainant emphasizes that section 3(c)(2)(A) of FIFRA, 7 U.S.C. § 136a(c)(2)(A), speaks to the "kinds of information" that the Administrator shall require. FIFRA nowhere defines this information and does not differentiate "between a statement or study and the information contained therein." The Agency has interpreted the applicable requirements in such a manner that it views a report to contain multiple kinds of information. It contends that the submission itself represents various kinds of information, and it considers each deviation from the GLPS as a separate piece of intelligence. Indeed, complainant notes that the Agency allows the sponsors of studies to point out specific deficiencies of the GLPS just so it may consider the effect of particular kinds of information on a study's reliability. 40 C.F.R. § 160.12. Thus, complainant maintains that the elements required to be submitted under the GLPS are "[a]mong the 'kinds of information that will be needed by the Agency to determine whether to register a product.'" (Opp'n at 4, 5, citing 45 Fed. Reg. 26,373, 26,383 (Apr. 18, 1980).)

These particular elements include "the information that the facility has a Quality Assurance Unit (40 C.F.R. § 160.35), the information documenting all changes in or revisions of an approved protocol (40 C.F.R. § 160.120), the information that documents the occasions and reasons for altering raw data (40 C.F.R. § 160.130(e)), etc." Complainant asserts that these elements are the independent kinds of information which the Agency has the ability to assess penalties for, and that this cannot be understood to implicate one indivisible whole. The basis of the GLPS is the submission of a study, not a statement of compliance. The statement of compliance is merely used to note deviations and alert the Office of Pesticide Program's registration division. Complainant contends that this requirement was not meant to consolidate all the various violations into one, but to signal the Agency as to the pieces of information in a study that are peculiarly suspect as a result of deviations from the GLPS. (Opp'n at 4-5.)

B. Aberrant Case Law

Complainant alleges that Bio-Tek was based upon inapposite case law. It opines that the order did not properly defer to the Agency's interpretation when Congress had not directly spoken on the issue, and the Agency interpreted its mandate in a reasonable fashion. (Opp'n at 8, citing In re Caschem, Inc. (Caschem), Docket No. II-TSCA-PMN-89-0106 (Oct. 30 1992), at 19, and referring to Chevron v. Natural Resources Defense Council, Inc. (Chevron), 467 U.S. 837 (1984).) Complainant is further of the view that more

appropriate than the FIFRA and criminal cases upon which Bio-Tek relied would be two Inventory Update Rule cases under the Toxic Substances Control Act (TSCA) that deal with the issues of deference and multiple penalty assessments. It argues that orders issued in, In re C. P. Hall Company, (C. P. Hall), TSCA-V-C-61-89 (June 9, 1992) and Caschem considered the appropriate unit of violation when inventory update forms (Forms U) were not submitted as required under pertinent regulations. The Administrative Law Judges (ALJs) involved in the aforementioned orders rejected the argument that the basis for the violation was the Form U itself and determined that there was a separate violation for each chemical not listed.

Complainant urges that, the proper analysis to be applied here is set forth in Caschem. Its view is that the initial step in analyzing a regulation is to determine whether Congress has directly spoken to the issue presented. If the intent of the statute can be determined from the plain language or the legislative history, the inquiry ends. If Congress is silent, then an ALJ must look to the Agency to determine whether it has interpreted the statute in a manner that constitutes Congressionally delegated lawmaking. If it has, one must generally defer. In the absence of a clear Congressional intent and formal Agency rulemaking, one is to consider informal policy documents, such as the ERPs. "Unless the interpretation regarding the number of violations is clearly erroneous, unfair, unreasonable, or is an

abuse of discretion, there is no reason not to uphold its application." Caschem at 19.

In Caschem and C. P. Hall, it was determined that the statutory language creating a cause of action, section 15(3)(b) of TSCA, 15 U.S.C. § 2602(3)(b), would support either interpretation. Moving to the statute from which the Inventory Update Rule was derived, section 8(a) of TSCA, 15 U.S.C. § 2607(a), it was again determined that the statute could be read to allow either single or multiple penalty assessments. Making an analysis for regulatory intent, it was found that the issue had not been addressed. However, it was concluded that there was no inconsistency between the Agency's interpretation and the regulation, (Opp'n at 10, 13, 14), and set forth the standard enunciated above.

Complainant analogizes the determinations made in C.P. Hall and Caschem to the situation here. It asserts that the penalty statute at issue, section 12(a)(2) of FIFRA,[4] provides no more guidance than that of TSCA section 15.[5] (Opp'n at 10, 11.) Neither statute addresses multiple penalty assessments directly. Moreover, in neither case does the regulatory language speak definitively to the issue. However, the ERPs for both TSCA's

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[4] Supra at 5.

[5] Section 15 of TSCA, in relevant part, provides that:
It shall be unlawful for any person to--
(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this chapter or a rule thereunder; . . . .

Inventory Update Rule and FIFRA's GLP do specifically provide for multiple violations. Furthermore, since the language of the applicable FIFRA provisions seems to allow more leeway than the analogous TSCA provisions, complainant asserts that there is absolutely no question as to the resolution of this conflict.

Complainant also contends that Bio-Tek's reliance on Hawk was inappropriate; that Blockburger was misapplied; and that the language that encompasses the violation in the former case is not analogous to that at issue here. "[I]t shall be unlawful . . . to distribute or sell to any person-- (E) any pesticide which is adulterated or misbranded." FIFRA § 12(a)(1)(E), 7 U.S.C. § 136j(a)(1)(E). This is clearly not the "all or part of any information" language that is at issue in this case. Section 12(a)(1)(E) of FIFRA discusses the sale of a pesticide which is misbranded. To create the analogous situation for the submission of reports, Congress could have dictated that it shall be unlawful to submit a study which does not conform to the GLPS. It did not. Congress stated that it shall be unlawful to falsify all or part of any information. This difference, according to complainant leads ineluctably to only one conclusion, that multiple violations are at issue. (Opp'n at 14.)

The alleged misapplication of Blockburger again flows from improperly reading "all or part of any information." Complainant asserts that "[t]he applicable rule is that where the same act or transaction constitutes a violation of two distinct statutory provisions, whether there are two offenses or only one, is whether

each provision requires proof of an additional fact the other does not." (Opp'n at 23, citing Blockburger at 304.) Complainant contends that Bio-Tek is defective in that it did not realize that proof of each aspect in which the "single statement" was false constituted a separate fact, and could be used to support a separate violation. In this case, complainant asserts that there are four distinguishable violations. Proof of each will require completely different facts.

C. Discussion and Conclusion

Before proceeding to a decision on the motion, it is stressed by the undersigned Administrative Law Judge (ALJ) that reasonable and honorable men can differ; he respectfully disassociates himself from the rationale and conclusion reached in Bio-Tek. To begin, certain factual distinctions between respondent and Bio-Tek should be noted. Bio-Tek and the instant matter differ in the nature of the "statement of compliance" submitted to fill the GLPS requirement of 40 C.F.R. § 160.12. In Bio-Tek, the respondent never actually submitted a statement as required under section 160.12. Rather, it submitted a "derivative" statement. This merely attests to the fact that another made the representations required of the respondent. Respondent here did make the required statement. In relevant part, it said "the study meets the requirements outlined in 40 C.F.R. 160." (Answer ¶¶ 12, 21, 30, 39) This factual distinction, however, does not give rise to a separate rule, and these cases cannot be distinguished. Though Bio-Tek

never submitted the required statement, it nonetheless made the same representations. In submitting its application for registration of a pesticide product, it had a responsibility either to comply with the GLPS or to provide the Agency with information regarding each deviation from the GLPS. 40 C.F.R. § 160.12(b). Absent the provision of this information, Bio-Tek must expect the Agency to act upon its application as if it were in compliance. The notion that Bio-Tek could shirk its responsibility by providing a representation which is truthful but inadequate for the purpose of 160.12 is utterly unpersuasive. Bio-Tek, through the submission of its application, represented to the Agency that the various elements of the GLPS were being complied with, and thus, this matter and Bio-Tek are for all practical purposes identical.

Bio-Tek's reading of the statute is entirely reasonable. However, it is not the province of an AlJ to reinterpret a regulation when the Agency has clearly stated policy which is consonant with its legal and regulatory mandate.

The Agency has discretion. In Chevron, the Supreme Court articulated the proper standard of review for federal courts to determine whether deference to a regulation's interpretation of a statute is appropriate. That test asks two questions:

1) Has Congress directly spoken to the precise question at issue?, and
2) Has the Administrator of the agency made a reasonable interpretation of the statute?

Chevron 467 U.S. 842. If the intent of Congress is clear, that is the end of the matter. If it is not, the Agency is entitled to

deference, and "a court may not substitute its own construction of a statutory provision." Id. at 844.

Extending this logic to the application of ERPs in Caschem, the ALJ there fashioned a similar standard for deference to the Agency's policy determinations. Where there has been no formal rulemaking, and the Agency has clearly stated its policy within the context of an ERP, "there is no reason not to uphold its application" unless the Administrator's interpretation is "clearly erroneous, unfair, unreasonable, or is an abuse of discretion." Id. at 19. Nowhere in the legislation, regulations or case law is there sufficient authority to read a mandate that:

> . . . a single statement or piece of information, which is false in more than one respect, submitted to the Agency in connection with a single transaction such as the studies at issue here, may not be turned into multiple violations for which multiple penalties may be assessed.

Bio-Tek at 21. As that case points out, the statutory history and legislative reports are far from enlightening. One of the only explanations "provides that certain acts (such as submitting false test data . . .) will be unlawful." H.R. 100-939, at 26 (1988), reprinted in U.S.C.C.A.N. at 3475, cited in Bio-Tek at 16. Bio-Tek holds that this is no indication that Congress intended multiple penalties. As complainant points out, however, this is no indication that Congress did not intend multiple penalties. If the intent is unclear, and the Agency's regulation interprets a statute in a reasonable manner, then that interpretation is entitled to deference. Chevron at 844.

In the GLPS regulations, there is an indication that the Agency considered the availability of multiple violations. In 40 C.F.R. § 160.17, addressing effects of non-compliance, it states that "[s]ubmission of a statement required by § 160.12 which is false may form the basis for cancellation, suspension, or modification of the research or marketing permit, or denial or disapproval of an application for such a permit, . . . or for imposition of civil penalties under FIFRA section 14." (Emphasis added.) Had the Agency considered there to be only one assessable violation for the submission of a false study, it could have so stated. However, it used the word "penalties" rather than the singular "penalty." Even if this indica is insufficient, this forum should defer to the Agency's interpretation as expressed through its ERP subject, of course, to the restrictions of Caschem. This being the case, analogies to other situations should only be made where a definitive answer is not to be found in the relevant statutes, regulations or agency policy documents. Since Bio-Tek did not find its answer in these materials, this ALJ will address the arguments and conclusions of that case. Bio-Tek analogizes its situation to a number of cases, both agency and federal, but these authorities cannot withstand analysis. The first case addressed in Bio-Tek is Hawk. It stands for the proposition that "where there is a violation of section 12(a)(1)(E) of [FIFRA] by reason of a shipment of a particular pesticide that is misbranded in more than one way, there is only one offense and only a single penalty may be imposed." The relevant portion of (a)(1) states that it "shall be

unlawful . . . to . . . sell . . . (E) any pesticide that is adulterated or misbranded." 7 U.S.C. § 136j(a). The ALJ in that case, Judge Levinson, found that FIFRA does not declare that each mode of misbranding is unlawful, but simply proscribes misbranding. Hawk at 10.

It is emphasized that the alleged violation here is not misbranding. It is the failure to submit information. The language of section 12(a)(2)(Q) of FIFRA quoted above is not the all-encompassing "it shall be unlawful to sell any pesticide that is misbranded" and does not lead inevitably to the same conclusions reached in misbranding cases. The section at issue states with specificity certain forms of information which it is unlawful to falsify. As complainant points out, Congress could have used language similar to that of the misbranding language in this situation. It could have enacted language that said it is unlawful to submit a false application. It did not. The statute makes illegal the falsification of "all or part of any information." It appears, at least to this ALJ, entirely reasonable to consider each deviation from the GLPS as distinct and demanding a separate penalty.

Since falsification of information may occur in many ways, it seems inappropriate to use Bio-Tek's transactional model. It creates a situation where the submission of a statement envelopes the various failures to comply with the GLPS. It is a myopic view in light of the goals of the GLPS. The basis of the GLPS is not the submission of a statement of compliance. Its purpose is to

provide the Agency with the requisite information to make an objective determination concerning the safety and utility of a pesticide product. See 40 C.F.R. § 160.1. In this vein, the Agency avers, with common garden intelligence, that each individual element of an application provides an independent indication as to the reliability of the data and information necessary for a proper evaluation.

It appears that the Agency has created the Statement of Compliance or Noncompliance not to consolidate the violations, but to provide an applicant some flexibility in its application for registration. Considering a situation without the section 160.12 statement of compliance, one would expect strict adherence to the standards, there would be no room for explanations, and the only common element of the violations would be that they are part of an application. As there is no language stating that it shall be unlawful to submit a false application, it seems clear that the falsification of "all or part of any information relating to the testing of any pesticide . . . " would provide for separate violations under the various provisions of the GLPS.

It is this ALJ's opinion that the provision of the ability to make a statement of compliance or noncompliance was incorporated not to restrict penalty assessments under section 12(a)(2)(Q)of FIFRA, but to account for the fact that people are human and they will err. When this occurs, the Agency allows applicants to explain deviations so that it may account for them in its processing of the application. When deviations are not noted or

explained, they can lead to inferior analyses, with the potential of disastrous environmental effect. Each deviation from approved practice is of independent significance, and without the provision of separate penalties, there is much less incentive to ensure compliance.

The unit of information comprising one violation is not measured by the amount of information that will fit on a particular size sheet of paper.[6] Rather, it relates to any and all pieces of "information" the Agency may deem necessary, within legal limits, to complete its statutorily imposed mission. A contrary interpretation would allow a violator to use section 160.12 as a shield against the assessment of more than one penalty where multiple digressions from the regulatory norm are included on one report or application for pesticide registration. Complainant states that there are in excess of twenty separate representations an applicant for a pesticide registration must make. To limit liability would provide little incentive for violators to ensure accurate entries in their reports. Such a limit might even provide an incentive to violate the GLPS. There is a clear difference between the person who makes one inadvertent misrepresentation and the person who makes twenty. It seems inherently unfair to subject the party that takes a great amount of care in preparing its application to the same potential liability as the party that makes numerous representations of a dubious nature.

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[6] The alternative being of course, that if the EPA wants multiple penalties, they should require each specific bit of information to be submitted on a separate form. See Bio-Tek at 20.

Returning to Hawk, it also considered the relevant law on criminal proceedings as the only difference between the civil and the criminal offense is the knowledge of the violator. That case incorporated the rule of Blockburger, which states that the test to be applied to determine whether there are two offenses or only one is whether each proposition requires proof of an additional fact the other does not. Judge Levinson's discussion about Azalea Dust in Hawk demonstrates how this test should be employed:

> This product was deficient in an active ingredient stated on the label. This resulted in misbranding because the label was false and misleading (section 2(q)(1)(A)) and also resulted in adulteration because the strength fell below the professed standard expressed on the label (section 2(c)(1)). Since proof of the same facts would support both charges a single penalty was imposed which may be attributed to the misbranding.
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> The product also contained an ingredient not stated on the label. This resulted in adulteration because a substance had been substituted for the pesticide (section 2(c)(2)) and also resulted in misbranding because the label was false and misleading (section 2(q)(1)(A)). Since proof of the same facts would support both charges a single penalty was imposed which may be attributable to adulteration.
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> The proof that was necessary to support the adulteration charge (substitution of a substance) was different from the proof that was necessary to support the misbranding charge (deficiency of an ingredient).

Hawk at 16. The false statement and the various deviations could, as in Hawk, all support the same violation, namely that of section 160.12. However, as Hawk makes abundantly clear, separate factual situations that could all be used to support a single violation,

can instead be used separately to make out various violations as appropriate under the GLPS.

Here, four distinct violations are alleged. Using the analysis of Hawk, one could attribute all four factual situations to one violation of 40 C.F.R. § 160.12, but one need not do so. The basis of the violation is not the Statement of Compliance. It is the submission of the study. These four violations would stand even without the allegation that a section 160.12 statement of compliance has been submitted. Support for the varied allegations necessarily comes from distinct factual situations, each requiring evidence the others do not.

The Agency does not allege simply that a misrepresentation occurred under section 160.12, but cites to varied provisions which can result in the faulty assessment of the risks of particular products that it must evaluate for registration.

One can even carry Hawk's analysis one step further. Blockburger stated that there is no:

> merit in the contention that the language of the penal section of the Narcotic Act, "any person who violates or fails to comply with any of the requirements of this act" shall be punished, etc., is to be construed as imposing a single punishment for a violation of the distinct requirements of §§ 1 and 2 when accomplished by one and the same sale.

Blockburger 284 U.S. at 305. From this language the result is obvious. The one report is akin to the one sale. The false application itself could constitute an offense, but that does not mean that distinct requirements of FIFRA must fall by the way because of that one transaction. There are distinct requirements

of the GLPS, and one need not construe those regulations to impose a single penalty.

It is true that there is a common thread that runs through all four of the violations alleged, but it does not make the four allegations identical, and certainly does not bind them into one. Each violation alleged arises out of a different set of facts. They could have been violations without a statement of compliance if the Agency had accepted the papers without the statement, or each omission could have been the sole ground for a violation of section 160.12. Bio-Tek would have allowed separate violations had the Agency required each representation to be on a separate piece of paper. It stated that, at least that way, potential violators would be on notice. To this ALJ, however, it appears that the language of the provisions in question provide all the notice that is necessary.

After utilizing Hawk, Bio-Tek determined that where the act is unclear, "well settled principles which resolve ambiguities in favor of lenity come into play." (Bio-Tek at 17, citing Heflin v. United States, 358 U.S. 415 (1959) and Bell v. United States, 349 U.S. 81,85 (1955).) The authorities cited for this proposition are both criminal cases. Though criminal cross-references may be useful for the proper interpretation of a statute, and elements of criminal interpretation are incorporated into civil proceedings, not every criminal maxim is directly applicable to the civil law. If it were, any unclear regulatory statute would be shackled to its

most narrow interpretation, and regulatory agencies would be relieved of much of their discretionary power.

FIFRA does not define information or the unit of violation, and Congress has not spoken to the "precise question" in either the statute or the legislative histories. Consequently, it is reasonable to interpret "any provision" in such a manner that GLPS provisions, other than the section 160.12 Statement of Compliance, may be entitled to separate penalty assessments when violations are brought to light in the submission of an application. Nor does it appear to be unreasonable, let alone clearly erroneous, to allow the Administrator to consider separate entries on an application for registration as separate pieces of information within the "all or part of any information" terminology. In fact, the Administrator's interpretation might very well be the most reasonable that has been given.

ULTIMATE CONCLUSION AND ORDER

Respondent wants this forum to believe that it has committed one violation under FIFRA, not four. This simply is not so. Each of respondent's alleged violations is different in kind from the others. These violations are not based on an affirmation. They rest upon the submission of a study. It was that, not the affirmation, which made the four violations come to light. Further, each separate violation is grounded upon a separate set of facts which in turn are the grounds for separately assessable violations.

For the reasons stated above, **IT IS ORDERED** that respondent's motion to reduce the counts in this proceeding be **DENIED**.

Frank W. Vanderheyden
Administrative Law Judge

Dated: November 17, 1993

CERTIFICATE OF SERVICE

I do hereby certify that the foregoing Order Denying Respondent's Motion To Reduce Counts In The Complaint From Four to One was filed in re Boehringer Ingelheim Animal Health, Inc.; Docket No. FIFRA-93-H-11 and that copies of the same were mailed to the following:

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Dated: Nov. 17, 1993